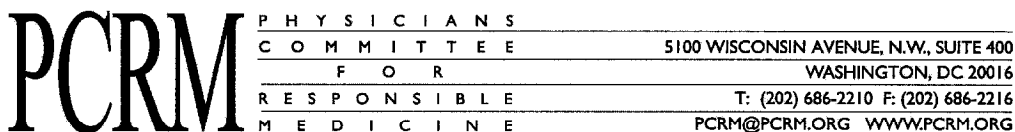


201-15403



June 25, 2004

Michael O. Leavitt, Administrator
US Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Avenue, NW
Washington, DC 20460

06 JUN 29 11:13:05
RECEIVED

Subject: Comments on the HPV test plan for the chemical 4-Nonanone, 2,6,8-trimethyl-

Dear Administrator Leavitt:

The following are comments on the test plan for the chemical 4-Nonanone, 2,6,8-trimethyl- (IBHK, CAS# 123-18-2) for the HPV program, submitted by The Dow Chemical Company (Dow). These comments are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These animal, health and environmental protection organizations have a combined membership of more than ten million Americans.

Dow proposes to do an OECD 422 screening protocol on this chemical, which will kill approximately 675 animals. Dow is also proposing to do a chromosomal aberration test, using OECD protocol 473, and an acute fish toxicity test, OECD 203. However, any comments submitted by interested parties are now moot since **Dow has already begun the proposed studies**. This is another violation of both the 1999 animal welfare agreement and the original HPV framework agreement, to which all the HPV participants agreed to adhere (Wayland 1999; Federal Register 2000). Both the EPA and the public are to be given the opportunity to comment on all test plans BEFORE any experimental work is undertaken. This test plan sets a disturbing precedent, as in a number of instances public commentators have been able to suggest ways in which proposed tests could be eliminated, resulting in the saving of a demonstrable number of animal lives.

In this particular case, we would have requested that Dow disclose in their Robust Summaries a study referenced in a technical letter from Dow to the EPA, containing the "results of a reproductive toxicity study with 2,6,8-trimethyl-4-nonanone in rats" (EPA/OTS; Doc #88020000147). While the content and details of this letter are unclear, the subject could represent results of an oral gavage study with rats conducted in 2002 by Dow. Therefore it is possible that there is available information on the endpoints that would be addressed in the OECD 422. If the study is unacceptable or invalid for some reason, the details still must be included in the Robust Summaries, in order to provide the public with all available information for the chemical. Furthermore, it is

incumbent upon Dow to explain the exact motivations behind prematurely conducting an OECD 422, given that public comments might have eliminated further testing.

Lastly, it is unclear whether Dow has considered the use of toxicity information from other chemicals that may share similar physicochemical or toxicological properties with IBHK, which is indefensible considering the common structure and chemical group of IBHK, i.e., a ketone with a linear nine-carbon chain, methyl groups at C2, C6, and C8, and a double-bonded O at C4.

Thank you for your attention to this issue. We ask that the EPA contact Dow and resolve the issue of its continuing and deliberate violations of the HPV program framework agreement, and look forward to a prompt and favorable response to our concerns from both Dow and the EPA. We can be reached at 202-686-2210 ext. 335 or via email at kstoick@pcrm.org.

Sincerely,

Kristie Stoick, MPH
Research Analyst

Chad B. Sandusky, PhD
Director of Research

References:

Federal Register Vol. 65, No. 248, December 28, 2000.

Wayland, S.H., "Letters to manufacturers/importers", October 14, 1999,
<http://www.epa.gov/chemrtk/ceoltr2.htm>.